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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/577,211 | 02/21/2007 | Hozumi Tanaka | 21581-00491-US | 3346 |

30678 7590 03/22/2011

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| EXAMINER | |
|---|---|
| SCHLIENTZ, NATHAN W | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/22/2011 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/577,211 | TANAKA ET AL. | |
| | Examiner | Art Unit | |
| | Nathan W. Schlientz | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4,6-16,18-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-16,18-20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

Claims 1, 2, 4, 6-16, 18-20 and 22-25 are pending in the present application and examined herein on the merits for patentability. No claim is allowed at this time.

It is noted that the status identifier of claim 21 states, "Cancelled". Therefore, the claim has been cancelled.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recites, "citric acid derivatives", "vitamin C derivatives", and "vitamin E derivatives". However, it is not clear what compounds are covered by the term "derivative". The broadest reasonable interpretation of derivatives of a compound covers all future improvements without regard to whether Applicants invented such improvements, which would undermine the function of the claims because it would allow Applicants to benefit from the ambiguity, rather than requiring Applicants to give proper notice of the scope of the claims to competitors. Additionally, adopting the broadest reasonable construction of the claims could retard innovation because cautious competitors may steer too far around that which Applicants actually

invented, neglecting improvements that otherwise might be made. See *Halliburton Energy Services Inc. v. M-I LLC*, 85 USPQ2d 1654 (Fed. Cir. 2008).

2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites, "A *powdery solubilized composition*". However, it is unclear what is meant by "powdery solubilized". A powder is a solid substance, wherein solubilized indicates the substance is dissolved in solution. The instant specification states that the term "solubilized" is used herein to indicate that the coenzyme Q in question is *dissolved* in the composition mentioned above and the whole or a part of the coenzyme Q is clathrated in the cyclodextrin (pg. 6, ln. 9-13). Therefore, it is not clear if the claim is drawn to a powder or a solubilized composition. It appears that the claim is intended to be drawn to a powdery composition that can be obtained by subjecting the composition according to claim 1 to spray drying, but it is not clear if after spray drying the composition is then solubilized.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 4, 6-16, 18-20 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 2002/0045596) in view of Fujii et al. (WO 02/092067; English-language equivalent US 2004/0115181 referred to herein).

*Determination of the scope and content of the prior art*

*(MPEP 2141.01)*

Nielsen et al. teach active ingredient combinations of cyclodextrins and at least one quinone and/or at least one hydroquinone (Abstract; and claim 1). Nielsen et al. teach that the cyclodextrins include α-cyclodextrin and γ-cyclodextrin ([0049] and [0051]; and claims 2 and 6). Nielsen et al. also teach that quinones include bioquinones, such as coenzyme Q10, and hydroquinones, include bioquinones, such as ubiquinols ([0043]-[0044]). Nielsen et al. further teach that the molecular adducts are prepared by dissolving cyclodextrins in water and adding the at least one quinone and/or at least one hydroquinone ([0080]). Nielsen et al. also teach that the weight ratio of cyclodextrins to the at least one quinones and/or at least one hydroquinones is 10:1 to 1:5, preferably 8:1 to 1:2, particularly preferably 4:1 to 1:1 ([0081]-[0083]). Nielsen et al. further teach that an additional content of antioxidants is generally preferred, such as

lycopene, glutathione, cysteine, citric acid, vitamin C, and vitamin E ([0109]). Therefore, Nielsen et al. teach compositions comprising cyclodextrin and ubiquinol (reduced coenzyme Q10), wherein the cyclodextrin is dissolved in water followed by addition of ubiquinol.

It is noted that the recitation of the intended use "the composition is used for oral administration" has not been given patentable weight to distinguish over Nielsen et al. because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Nielsen et al. teach compositions that are the same as those claimed, they would be capable of performing the intended use, as claimed.

It is noted that claims 12 and 13 are drawn to a product but defines a process by which that product can be obtained (i.e., can be obtained by subjecting the composition according to claim 1 to spray drying; and can be obtained by mixing the polar solvent, the cyclodextrin and the reduced coenzyme Q). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product

was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). See MPEP 2113.

With regard to claim 24 and the limitation that the whole or a part of the reduced coenzyme Q is clathrated in the cyclodextrin, the process of Nielsen et al. is identical to the process being claimed, dissolving cyclodextrins in water followed by addition of the coenzyme Q. Therefore, the products of Nielsen et al. will inherently meet the limitations of the instant claims.

*Ascertainment of the difference between the prior art and the claims*

*(MPEP 2141.02)*

Nielsen et al. do not explicitly teach that the hydroquinones, which include bioquinones such as ubiquinols, include reduced coenzyme Q as instantly claimed. However, Fujii et al. teach compositions comprising oxidized coenzyme Q and reduced coenzyme Q; wherein the reduced coenzyme Q are identical to the instantly claimed reduced coenzyme Q ([0007]-[0010]).

Nielsen et al. do not explicitly teach that the proportion of hydroquinone (reduced coenzyme Q) to the sum of quinone (oxidized coenzyme Q) and hydroquinone is not smaller than 50% by weight (i.e., at least 50% by weight of the combination is hydroquinone). However, Fujii et al. teach compositions comprising oxidized coenzyme Q and reduced coenzyme Q; wherein the content of reduced coenzyme Q of the whole of oxidized coenzyme Q and reduced coenzyme Q preferably exceeds 20% by weight, and is more preferably 40% by weight or more; wherein the upper limit of the content

may be 100% by weight or less, preferably less than 100% by weight, and more preferably 98% by weight or less ([0018]).

*Finding of prima facie obviousness*

*Rational and Motivation (MPEP 2142-43)*

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to prepare the compositions of Nielsen et al. comprising a combination of quinone (oxidized coenzyme Q) and hydroquinone (reduced coenzyme Q1-12), wherein the reduced coenzyme Q1-12 is present in equivalent or greater amount than the oxidized coenzyme Q, as reasonably suggested by Fujii et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Response to Remarks***

Applicant noted on page 10 that Fujii et al. relates to an aqueous solution containing a reduced coenzyme Q and an antioxidant and/or a chelating agent; Fujii et al. solubilizes the reduced coenzyme Q by using a liposome or a surfactant. However, Fujii et al. do not at all disclose the cyclodextrin.

The examiner respectfully directs attention to Madhavi et al. (US 7,030,102) wherein Madhavi et al. teach that complexation in general with γ- or α-cyclodextrin improved the cellular uptake of CoQ-10 as compared to water dispersible liposomal or

micellar forms of CoQ-10 (Abstract). Therefore, it would have been obvious to prepare the reduced coenzyme Q and its combinations with oxidized coenzyme Q by complexation with cyclodextrin in order to improve cellular uptake as compared to the liposomal or micellar forms.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-

272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616